# Request for Information – PCR Sample Collection Kit

|  |  |
| --- | --- |
| **Supplier Name** |  |
| **Contact Name** |  |
| **Contact Email Address** |  |
| **Contact Tel Number** |  |

**| Instructions:**

* 1. The purpose of this document is to enhance the Authority’s understanding of the marketplace and its options for sourcing for a potential future requirement.
  2. The issuance of this request for information (RFI) does not constitute a sourcing exercise nor will the Authority pay any costs incurred in the preparation of a response to this RFI.
  3. The UK Health Security Agency’s (UKHSA) key objectives for this RFI are:
  4. understand the ability of the marketplace to fulfil its requirements;
  5. refine the scope of the requirements to best align to the marketplace; and
  6. inform the Authority’s chosen route to market to best enable competition
  7. The key dates for this RFI are as follows:

1. **RFI Published: Friday 22nd August 2025**
2. **RFI Response Deadline: 17:00 on Monday 15th September 2025**
   1. Should you have any questions or queries relating to this RFI, please use the Atamis portal’s messaging centre to direct your questions to us for a response.
   2. If a response is not received by the RFI response deadline this will have no impact on your ability to tender for the opportunity in the future. UKHSA will not enter into contracts on the basis of replies to this RFI.

**| Description of Scope of Requirements:**

The UK Health Security Agency (UKHSA) is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation's health secure.

UKHSA uses PCR sample collection kits as a critical tool in protecting public health, providing support in outbreak investigations and control measures for a range of pathogens including SARS-CoV-2 and H1N2

To provide greater resilience and flexibility across use cases as part of UKHSAs Pandemic Preparedness strategy and support the UK’s contribution to the [100 Days Mission - GOV.UK](https://www.gov.uk/government/publications/100-days-mission-to-respond-to-future-pandemic-threats), which targets deployment of diagnostics within 100 days of identifying a new pandemic threat, it would be beneficial to identify a suitable standard VTM self-collection PCR sample collection kit that could either be procured for central stockpile or acquired at the point of need.

The UKHSA requires a UKCA/CE approved self-collection PCR sample collection kit that is easy to access, simple and intuitive to be used by the UK public (with no required specialist training and with minimal technical jargon).

​In addition, UKHSA is also seeking to understand the availability of turnkey services that could support the PCR product and inform our choice of delivery model, including co-packing, fulfilment, and warehousing solutions. These services would further strengthen our capacity to respond rapidly and at scale to both known and emerging infectious diseases.

​

**Questions**

1. Can you supply a complete individual self-sample PCR collection kit that includes a swab and vial, return packaging with barcodes, and holds UKCA/CE or equivalent regulatory approvals for self-collection of samples?
2. Can you provide any and/or all the following services: co-packing and fulfilment, use of customisable barcodes, direct-to-lab/patient delivery, returns tracking, warehousing, logistics, and API/electronic order system integration? Please specify which you can provide as part of your response.
3. Please provide full kit and manufacturer details, including brand and assay name (as it appears on label/IFU), manufacturers product code, legal manufacturer and UK representative (if applicable), and a description of components (swab, vial – including dimensions, media type).
4. Please provide the latest Instructions for Use (IFU), including version and revision date, and indicate if a different version was used in regulatory submissions, providing the copy used for regulatory submission.
5. Please provide the intended use statement, and confirm it is manufactured in an ISO 13485 accredited facility?
6. What other certifications or accreditations does your organisation or manufacturing site hold (e.g., ISO 9001, ISO 10993, GMP)?
7. Do you operate a defined batch release process, and has the product been subject to any recalls or Field Safety Notices in the past 3 years?
8. What is the product’s shelf life and stability under various storage conditions aligned to your regulatory approvals, and do you have access to a warehouse temperature controlled or monitored?
9. Which regulatory frameworks apply to the device (e.g., UK MDR 2002 (as amended), EU IVDR), and is the device UKCA/CE marked for its intended use?
10. Please provide regulatory documentation, including CE/EC Declaration of Conformity or UKCA certificate number/UDI, or internal reference if self-declared.
11. Is the product for research use only, and does it have a latex-free declaration?
12. Are you listed on any UK government frameworks, DPS, or Dynamic Markets through which UKHSA could procure your PCR sample collection kit?
13. Please provide details regarding your supply chain for materials and/or components related to the PCR sample collection kit, please provide lead times, shipping methods and confirm whether you maintain or could maintain a stockpile of those components/materials and for what quantity of PCR sample collection kit.
14. Please provide commercial and supply details, including country of manufacture, pack size, unit of issue, indicative unit price (GBP), inclusive of price breaks by volume and weekly supply capacity.
15. What are your current lead times for manufacturing and delivery, and what is your average turnaround time from order receipt to dispatch?
16. What is your fulfilment capacity and scalability, including current daily capacity and your timescales and capability to ramp up to 100,000 consignments per day? Please also confirm how long you would be able to sustain this once the 100,000 consignments per day is met.
17. Do you offer fully integratable Electronic Data Interchange (EDI) and/or API connections with order management systems? And if so, what order management, inventory, and shipping platforms do you currently integrate with? Can you integrate with others, if so which ones?
18. Which courier and freight providers do you currently partner with, and what service levels do you support? Are you able to offer 24-hour delivery across all regions of England, including rural areas? And do your delivery services have end-to-end tracking?